

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1 and 6 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The examiner states that priority documents including US appl. nos. 07/930,443; 07/524,263; 08/450,972; and 08/115,685 were not available to the examiner and therefore the priority of the instant claims could not be determined. Furthermore, the examiner states that references filed in the priority applications and identified in the instant application on PTO-1449, copies of which references are not required to be filed in the present application, have not been considered because the files of the priority applications are unavailable to the examiner.

This situation is absurd. Applicant has properly identified the prior applications on which the benefit of priority is claimed both in the first sentence(s) of the specification and on an Application Data Sheet (ADS). While applicant is attaching copies of US appl. no. 07/534,263 (US appl. no. 07/930,443 is a Rule 62 continuation of 07/534,263 and has the same specification) and Israeli priority document

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IL 091229 for the examiner's convenience, applicants have not supplied copies of the references cited the prior applications. The examiner and the USPTO are requested to locate the files of the priority documents and consider the references cited therein that are listed in the PTO 1449 forms filed with the instant application. Support for the present claims is found at page 16, lines 2-13 and Example 8 on pages 31-33 of 07/534,263 and at page 2, last paragraph, of IL 091229.

The "Cross-Reference to Related Applications" section on page 1 of the present specification specifically incorporates US appl. no. 07/534,263, by reference. Applicants are amending Example 4 of the instant specification to physically incorporate the additional experimental results on determination of TBP-II using anti-TBP-II antibodies from pages 32-33 of prior US appl. no. 07/930,443. There is no new matter being introduced into the present specification.

Claims 1 and 6 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is believed to be obviated by the amendments to the claims. The indefiniteness issue regarding "over production" and "under production" is discussed below with the enablement rejection.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1 and 6 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

It appears that the examiner is taking the position that the claims require that some disease be diagnosed. However, this is not the case. The claims do not require that any particular disease be diagnosed. It is useful to know whether a subject has an overproduction or underproduction of TBP-II as a diagnostician would be able to use that piece of information, along with all of the other pieces of information that he has obtained from his examination of the subject, in order to make a diagnosis. Applicants are not claiming that overproduction or underproduction definitely means that the person has a certain disease. Rather, the examiner is imputing to the claim something that is not there. It is trivially easy to determine levels of TBP-II in body fluids and to compare those levels from one sample to another. This is all that is required of the claims. It is believable that if a level is above normal there is overproduction and if the

level is below normal there is underproduction. It does not matter that the claims do not define how much above normal is necessary for there to be overproduction. One of ordinary skill in the art would be able to factor in the amount of overproduction or underproduction without undue experimentation and would recognize and understand what is overproduction and what is underproduction. In other words, that will be a factor to take into consideration in making the diagnosis, just as every other factor.

As indicated above, applicants have also physically incorporated into the preset specification from prior application no. 07/930,443 experimental results from SLE patients to demonstrate examples of overproduction that is highly correlative of a disease state. However, it is reemphasized from the arguments presented above that there is enablement even in the absence of these further experimental results.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claim 6 has been rejected under 35 U.S.C. §112, first paragraph, as lacking written description. This rejection is obviated by the amendment to claim 6 to recite residues 27-214 of SEQ ID NO:3.

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Claims 1 and 6 have been rejected under 35 U.S.C. §102(a)(b) as being anticipated by Brockhaus et al. (EP 03341665, published September 27, 1989) and under 35 U.S.C. §103(a) as being unpatentable over Brockhaus et al. EP 0334165 in view of Wolpe et al. (US Patent 5,700,466) and additionally in view of Brockhaus et al. (US Patent 5,610,279). These three prior art rejection are made moot because the primary Brockhaus et al. EP 0334165 reference, published September 27, 1989, is antedated by the IL 091229 priority application filed August 6, 1989, and is therefore unavailable as prior art.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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